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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact:

Paul S. Lee
Senior Regulatory Affairs Specialist

Device Identification:

Common Name:
Perforated Bioabsorbable Interference Screw

Trade Name: (optional)
KSEA Perforated Bioabsorbable Interference Screw MegaFix™

Indication: The KSEA Perforated Bioabsorbable Interference Screw MegaFix™ is intended for use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction.

Device Description: The KSEA Perforated Bioabsorbable Interference Screw MegaFix™ is biocompatible and biodegradable.

Substantial Equivalence: The KSEA Perforated Bioabsorbable Interference Screw MegaFix™ is substantially equivalent to the predicate devices since the basic features and intended use are similar. The minor differences between the KSEA Perforated Bioabsorbable Interference Screw and the predicate devices raise no new issues of safety and effectiveness, as these minor differences have no effect on the performance, function or intended use of the device.

Signed: _____

Paul S. Lee
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2003

Mr. Paul S. Lee
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230

Re: K030848
Trade/Device Name: KSEA Perforated Bioabsorbable Interference Screw MegaFix™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 17, 2003
Received: March 17, 2003

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 03 0848

510(k) Number (if known): Not yet assigned

Device Name: KSEA Perforated Bioabsorbable Interference Screw MegaFix™

Indications for Use: The KSEA Perforated Bioabsorbable Interference Screw, MegaFix™ is intended for use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes OR Over-The-Counter Use: No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030848